MAR 2 3 2006

SUMMARY OF SAFETY AND EFFECTIVENESS

NAME OF FIRM:
DePuy Orthopaedics Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988
EST REG No.: 1818910

510(K) CONTACT:
Steve Wentworth
Regulatory Affairs Manager
Tel: (574) 371-4913
Fax: (574) 371-4987

TRADE NAME:
DePuy PFC® Sigma Knee Prosthesis

COMMON NAME:
Tricompartmental Knee Prosthesis

CLASSIFICATION:
Knee joint patellofemorotibial, polymer/metal/polymer semi-constrained cemented prosthesis (21 CFR 888.3560), Class II Device

DEVICE PRODUCT CODE:
JWH

SUBSTANTIALLY EQUIVALENT DEVICES:
DePuy LPS Metaphyseal Sleeve Component
(K040281, cleared July 9, 2004)
Darwin Knee System (TC3)
(K952830, cleared January 18, 1996)

DEVICE DESCRIPTION:

The DePuy Sigma Femoral Adapters are a modification to the previously cleared DePuy PFC Sigma Femoral Adapters included in K040281. The devices consist of a selection of adapters and bolts that attach to Sigma TC3 and C/S femoral components' intracondylar boxes. When assembled to a femoral component, they provide a construct for the attachment of additional fixation extensions such as metaphyseal sleeves or cemented and fluted stem extensions. The Sigma Femoral Adapters are available in five and seven degree valgus angle options and +2 mm, 0 mm, and –2 mm anterior/posterior offset options.

INDICATIONS FOR USE:

The PFC® Sigma Total Knee Prosthesis is intended for use in total knee replacement surgery for patients suffering from severe pain and disability due to permanent structural damage resulting from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, pseudogout, trauma or failed prior surgical intervention. The PFC Sigma Total Knee Prosthesis is intended for cemented use only.

BASIS FOR SUBSTANTIAL EQUIVALENCE:

The design of the PFC Sigma Knee Prosthesis Femoral Adapter is substantially equivalent to the LPS Metaphyseal Sleeve (K040281) and the Darwin Knee System (TC3) (K952830). The materials used for the subject device components are identical to those for the predicated devices and the design of the attachment mechanism incorporates similar adapter, retaining ring and bolt components. The available offset options (2mm anterior, neutral, 2mm posterior) are the same for the PFC Sigma and the predicate devices. Both the PFC Sigma and Darwin Knee systems offer 5^0 and 7^0 valgus angle components, whereas the LPS system offers only a 5^0 valgus angle component.

Based upon the similarities in the design, the equivalent materials utilized and the results from the mechanical testing of the PFC Sigma Femoral Adapter, DePuy believes this device to be substantially equivalent to other commercially available devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 3 2006

DePuy Orthopaedics, Inc.
c/o Mr. Steven J. Wentworth
Regulatory Affairs Project Manager
P.O. Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K060515
Trade/Device Name: DePuy Sigma Knee Femoral Adapter
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JWH
Dated: February 24, 2006
Received: February 27, 2006

Dear Mr. Wentworth:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

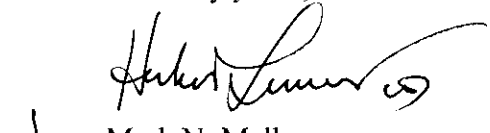
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K060515

Device Name: DePuy Sigma Knee Femoral Adapter

Intended Use and Indications:

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Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K060515